510(k) Summary

Altaravision K131873

This 510(k) Summary is in conformance with 21CFR 807.92

Submitter: Altaravision, Inc.
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Apex, NC 27502

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Company Contact: Stuart Bradley
Chief Executive Officer

SEP 2 5 2013

Date Prepared: June 18, 2013

Device Name and Classification

Trade Name:	NDŌHD High Definition Imaging System (NDŌHD)
Common Name:	Picture Archiving Communications System (PACS)
Classification:	Class II
Regulation Number:	892.2050 – Picture Archiving and Communications System (PACS)
Classification Panel:	Radiology
Product Code:	LLZ

Predicate Device

Trade Name:	Digital Video Recording System
Common Name:	System, Image Processing
510(k) Submitter / Holder:	Kay Elemetrics Corp.
510(k) Number:	K991738
Regulation Number:	892.2050 – Picture Archiving and Communications System (PACS)
Classification Panel:	Radiology
Product Code:	LLZ

Device Description and Intended Use

The NDÕHD High Definition Imaging System (NDÕHD) was initially commercialized in 2011 as a photographic accessory for endoscopes (FEM), Class I Exempt device. Altaravision has expanded the capabilities of the NDÕHD system to include a computer and a camera, included a lossy image compression mechanism using standard irreversible compression technique, H.264, added a time code on the display of the image, created camera controls and added profiles for multiple camera settings and user preferences. Therefore, Altaravision has created a picture archiving and communication system that provides capabilities related to the acceptance, transfer, display, storage and digital processing of images and videos. Based on the new system functions and the use of the device, the NDÕHD system is now considered a Class II device and requires a premarket approval.

The NDÕHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic procedures.

Indications for Use

The NDÕHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic procedures. The professionals or practitioners using this system would be medical doctors or clinicians such as speech pathologists. The device is a prescription device. The NDÕHD system is not intended to be used in an environment that requires sterilization.

Substantial Equivalence:

The NDÕHD system is substantially similar to a predicate device currently on the market. This device is:

- Digital Video Recording System (DVRS) - K991738

Both devices use very similar technologies, overall design and operating principals.

The primary differences in the technology between the NDÕHD System and the DVRS are described in the table below:

Detailed Comparison of the Subject and Predicate Devices

Item	Subject Device NDÕHD High Definition Imaging System (NDÕHD)	Predicate Device Digital Video Recording System (DVRS)	Comparison
Intended Use	The NDÕHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic	The intended use of the DVRS is for viewing, acquiring, recording, archiving and retrieving video images of	Same as predicate

Item	Subject Device NDÖHD High Definition Imaging System (NDÖHD)	Predicate Device Digital Video Recording System (DVRS)	Comparison
	procedures.	endoscopic and fluoroscopic procedures	
Indications for Use	The NDÖHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic procedures. The professionals or practitioners using this system would be medical doctors or clinicians such as speech pathologists. The device is a prescription device. The NDÖHD system is not intended to be used in an environment that requires sterilization.	The intended use of the DVRS is for viewing, acquiring, recording, archiving and retrieving video images of endoscopic and fluoroscopic procedures. The images may be monochrome or color. The professionals or practitioners using this system would be medical doctors or clinicians such as speech pathologists. The device is a prescription device.	Same as predicate
Target Population	Medical doctors or clinicians such as speech pathologists	Medical doctors or clinicians such as speech pathologists	Same as predicate
Display	Built-in computer display	NEC MultiSync E900+	Similar to predicate
Storage Medium	Non removable hard drive	Removable 2Gb hard drive	Similar to predicate
Video Output Format	.mov H.264 Video and .tiff still images	MJPEG and AVI	Similar to predicate. Predicate uses Windows specific formats, while the NDÖHD system is using an OS agnostic format.
Camera CCD (charge discharge)	1032x762 CCD. 1/3" sensor, 31 FPS (Frames per second) progressive scan, 800Mb/s, bit depth: 8-14 bit.	Optional	The use of a camera is optional for the predicate

Item	Subject Device NDÕHD High Definition Imaging System (NDÕHD)	Predicate Device Digital Video Recording System (DVRS)	Comparison
Lossy Image Compression	Yes, H.264 compression	Yes	Similar to predicate. The exact compression type of the predicate is unknown
Energy	Computer built in battery operated	UPS battery operated	Similar to predicate. Both systems use battery during operation. The NDÕHD system provides safety controls to prevent operators from using the device while plugged into an AC power outlet.
Software	NDÕHD Software used to control the recording, playback, storage, retrieval, and live view of high definition video (.mov), audio and images (.tiff) data.	DVRS Software used to control the recording, playback, storage and retrieval of digital video (MJPEG images) and audio data.	Similar to predicate. The NDÕHD Software provides a live view of the procedure in progress. NDÕHD Software is developed using Macintosh-compatible technology. DVRS is developed using Microsoft-compatible technology.

Testing

Software Validation and Electrical Safety Testing have been completed according to FDA Guidance documents and Industry Standards as follows:

- General Principles of Software Validation; Final Guidance for Industry and FDA Staff, January 11, 2002
- Guidance for the Submission of Premarket Notifications for Medical Image Management Devices, July 27, 2000
- IEC 60601-1: 1998+A1:1991+A2:1995+ Am.11+ Am.12 + Am.13:1996, Medical Electrical Equipment Part 1-2: General Requirements for Safety
- IEC 60601-1-1, Ed 2.0, Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems
- IEC 60601-2-18: 2009, Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment

Laboratory data is not required. The NDŌHD system utilizes standard irreversible compression techniques (H.264).

Substantial Equivalence Conclusions

In conclusion, the intended use for the NDŌHD system is the same as that of the predicate device, the technological characteristics demonstrate that the NDŌHD system is equivalent to the predicate device, and the testing shows that the NDŌHD system is substantially equivalent to the predicate device and assures that the NDŌHD system is as safe and effective as the predicate devices.

Conclusion

The 510(k) Pre-market Notification for the NDŌHD system contains adequate information and data to determine that the NDŌHD system is as safe and effective as the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 25, 2013

Altaravision Incorporated
% Ms. Rita King
CEO
PO Box 110352
Durham, North Carolina 27709

Re: K131873
Trade/Device Name: NDŌ$_{HD}$ High Definition Imaging System (NDŌ$_{HD}$)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 18, 2013
Received: June 27, 2013

Dear Ms. King:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Long H. Chen -A

For

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K131873

Device Name: NDÖHD High Definition Imaging System (NDÖHD)

Indications for Use

The NDÖHD system is intended for viewing, acquiring, recording, archiving and retrieving video and still images of endoscopic and fluoroscopic procedures. The professionals or practitioners using this system would be medical doctors or clinicians such as speech pathologists. The device is a prescription device. The NDÖHD system is not intended to be used in an environment that requires sterilization.

Prescription Use Yes (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use No (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Neil R Ogden -S
2013.09.25 10:04:33 -04'00'

(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K131873